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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,495	01/15/2004	James H. Silver	JSILVER.1CP2CP	6182

20995 7590 07/12/2006

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EXAMINER
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NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/758,495		SILVER ET AL	
	<b>Examiner</b>		<b>Art Unit</b>	
	Robert L. Nasser		3735	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/05 &amp; 3/16/06</u> . | 6) <input type="checkbox"/> Other: _____  |

The examiner notes that none of the prior applications detect nitric oxide or a metabolite thereof. Accordingly, claims 25-37 have a filing date only of the current application, or January 15, 2004.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57 and 60 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 57 and 60 lacks a written description in that the specification does not discuss the streamlined sensor on a catheter or opening through a side wall of a support. Since these are new claims, they constitute new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68, 70-73, and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebel et al 2004/0236201. Lebel et al shows a catheter having a sensing end comprising a sensor support 30 holding an oxygen sensor 20, noting that oxygen is a metabolite of NO. The device further has a sensor housing 22, where the sensor is exposed to outside of the housing via an opening in the sidewall of the housing. With respect to claim 72, the sensor is on the luminal side of the support, depending on the orientation of the device, noting that applicant has not defined to what structure the lumen belongs.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55, 56, 58, 59, 61-66, 69, 71, 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver 6442413 in view of Lebel et al. Silver 6442413 qualifies as art under 102 (a) and (b) and hence is useable in a 103 rejection. Silver shows a glucose sensor housing having a sensing surface exposed to the blood, that is mounted on a stent, which is an expandable mesh. The device further has an eptfe coating on the outward side of the device. The sensor further has a streamlined configuration. It does not sense nitric oxide or a metabolite thereof. However, Lebel

teaches that the same device may measure either glucose or nitric oxide. Hence, it would have been obvious to modify Silver to measure nitric oxide, as it is merely the substitution of one known analyte for another. Claim 59 is rejected in that the sensor is on the luminal side of the support, depending on the orientation of the device, noting that applicant has not defined to what structure the lumen belongs. Claims 64 and 65 are rejected in that Silver uses an amperometric or ion-selective electrode. With respect to claim 66, the device of Silver an enzyme gel layer beneath a membrane (see Silver, column 5, lines 30-31). Claims 69, 71, and 74-78 are rejected for the reasons given above.

Claim 67, 79, and 80 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Silver in view of Lebel et al, as applied to claims 55, 56, 58, 59, and 61-66 above, and further in view of Kaylor et al 2005/0101841. Lebel further teaches that ions related to nitric oxide may be measured. Kaylor teaches that it is desirable to monitor nitrate level, which is an ion related to NO. Hence, it would have been obvious to modify the combination to measure nitrate, as it is merely the substitution of one known equivalent analyte for another. Kaylor et al further teaches that when detecting Nitrate, it is well known to use nitrate reductase as the enzyme. Hence, it would have been obvious to modify the above combination to use nitrate reductase, as it is merely the substitution of one known equivalent enzyme for another.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

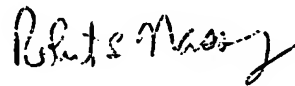
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser  
Primary Examiner  
Art Unit 3735

RLN  
July 10, 2006



ROBERT L. NASSER  
PRIMARY EXAMINER